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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/644,288 | 08/20/2003 | Paul Diamond | PT100-3 | 5798 |

7590 12/14/2005

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| EXAMINER |
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POPA, ILEANA

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| ART UNIT | PAPER NUMBER |
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1633

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/644,288 | DIAMOND, PAUL | |
| | Examiner | Art Unit | |
| | Ileana Popa | 1633 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1-36 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16, drawn to a method for regulating the expression of a preselected gene in a cell, classified in class 435, subclass 375.

- II. Claims 17-24, drawn to a method for excising a preselected DNA sequence from a cellular genome, classified in class 435, subclass 375.

- III. Claims 25-36, drawn to a method for bringing the expression of a preselected gene in a cell under the control of a preselected promoter, classified in class 435, subclass 375.

3. Should group I be elected for prosecution, a further group restriction is required to one transcriptional regulator and one multi-cellular organism. Applicant is required to elect one group from each category, as follows:

Transcriptional regulator

- I(i). Claims 1, 9, and 16, drawn to a transcriptional regulatory protein.

- I(ii). Claims 6, 9, and 16, drawn to a transcriptional regulatory RNA.

Multi-cellular organism

- I(iii). Claim 14, drawn to a transgenic animal.

- I(iv). Claim 15, drawn to a transgenic plant.

Claim 9 links inventions of groups II(iii)-II(iv). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 9. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Should group II be elected for prosecution, a further group restriction is required to one polynucleic acid molecule, as follows:

II(i). Claim 21, drawn to a viral polynucleotide acid molecule.

II(ii). Claim 23, drawn to a cellular RNA.

II(iii). Claim 24, drawn to a viral RNA.

Claim 22 links inventions of groups II(ii)-II(iii). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 22. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the

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limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. Should group III be elected for prosecution, a further group restriction is required to one type of promoter and one type of multi-cellular organism. Applicant is required to elect one group from each category, as follows:

Promoter

III(i). Claims 26 and 31, drawn to a transiently-active promoter.

III(ii). Claims 27 and 32, drawn to a constitutively-active promoter.

III(iii). Claims 28 and 33, drawn to a inducible promoter.

Multi-cellular organism

III(iv). Claim 35, drawn to a transgenic animal.

III(v). Claim 36, drawn to a transgenic plant.

Claim 29 links inventions of groups III(i)-III(v). The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 29. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions

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shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. The inventions of groups I-III are patentably distinct from each other because they are directed to methods that are distinct both physically and functionally, are not required for one another and result in different products. For example, steps and compositions in regulating the expression of a preselected gene in a cell by RNA silencing of the transcriptional regulatory factor for that gene, steps and compositions for selectively excising a preselected DNA sequence from a cellular genome using a repressible promoter operably linked to a gene encoding for a site specific recombinase and causing RNA silencing of the repressor protein for that promoter thereby activating the promoter, and steps and compositions for bringing the expression of a preselected gene under the control of a preselected promoter wherein the promoter is linked to the preselected gene via a blocking sequence that is removed when a site-specific recombinase is expressed are all different from each other.

The inventions of groups I(i) and I(ii) are patentably distinct because they are drawn to proteins that are structurally distinct, do not appear to have any substantially common structure that would impart critical functionality and, therefore have different utilities. A search and examination of operation, functional effect, and patentability would be distinct for each. Therefore, a search and examination of anything more than one of the above designated groups would be a serious burden for the examiner.

The inventions of groups I(iii) and III(v) are patentably distinct from the inventions of groups I(ii)-III(v) because they are drawn to multi-cellular organisms that are structurally distinct, do not appear to have any substantially common structure that would impart critical functionality and, therefore, have different utilities. A search and examination of operation, functional effect, and patentability would be distinct for each. Therefore, a search and examination of anything more than one of the above designated groups would be a serious burden for the examiner.

Similarly, the inventions of groups II(i)-II(iii) are patentably distinct because they are drawn to nucleic acids that are structurally distinct, do not appear to have any substantially common structure that would impart critical functionality and, therefore, have different utilities. A search and examination of operation, functional effect, and patentability would be distinct for each. Therefore, a search and examination of anything more than one of the above designated groups would be a serious burden for the examiner.

The inventions of groups III(i)-III(iii) are patentably distinct because they are drawn to promoters that are structurally distinct, do not appear to have any substantially

common structure that would impart critical functionality and, therefore, have different utilities. A search and examination of operation, functional effect, and patentability would be distinct for each. Therefore, a search and examination of anything more than one of the above designated groups would be a serious burden for the examiner.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Ileana Popa

A handwritten signature in black ink, consisting of a stylized 'D' followed by a long, sweeping horizontal line that extends to the right.

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER